REMARKS

In the Office Action mailed March 01, 2006, Claims 1, 2, 5-17, 24-37, 39-66, 72-87, 94-107, and 109-133 were pending for consideration in the present application. All of such claims were rejected under 35 U.S.C. § 103(a) as allegedly obvious in view of one or more cited references. It is respectfully requested that the Examiner further consider the application in view of these remarks.

Rejections Under 35 U.S.C. § 103

The Examiner has rejected claims 1, 2, 5-17, 24-37, 39-66, 72-87, 94-107, and 109-133 under 35 U.S.C. 103(a) as being allegedly unpatentable over U.S. Patent No. 6,096,338 (hereinafter "Lacy") alone or as being allegedly unpatentable over Lacy in view of U.S. Patent No. 4,897,269 (hereinafter "Mezei"). The Applicant respectfully submits that these claims are patentable over the cited reference for the reasons set forth below, and that the rejection should be withdrawn.

While Applicants are confident that the Examiner is well acquainted with the requirements necessary to establish a *prima facie* case of obviousness, it is thought prudent to briefly review the required elements. Specifically, in order to meet the burden of establishing a *prima facie* case of obvious, the Patent Office must show that: 1) each and every element of the invention as set forth in the claims is taught or suggested by the reference as modified; 2) that there is sufficient motivation contained in the reference itself or the knowledge of one of ordinary skill in the reference to modify or combine the reference; and 3) that one of ordinary skill in the art would find a sufficient likelihood of successfully making the modification or combination asserted. Applicants respectfully submit that the Examiner has failed to satisfy these requirements with any of the asserted rejections.

The Present Invention

The present invention, as recited in independent Claim 1, provides for a pharmaceutical formulation having an active agent and a pharmaceutically acceptable vehicle. The active agent is found in two fractions, a solubilized fraction and a solid particle fraction. The solid particle fraction and the solubilized fraction are both present in the pharmaceutically acceptable vehicle. The solid particle fraction represents from about 5 wt% to about 80 wt% of the active agent and the solubilized fraction represents from about 20 wt% to about 95 wt% of the pharmaceutical

formulation. The presence of the active ingredient in both a solubilized form and a solid form is an important element to the current invention.

Likewise, independent Claim 74 of the present application teaches a pharmaceutical system for the administration of an active agent, which also requires that the active agent be present in both a suspended or solid particulate phase and a solubilized phase.

Rejection in view of Lacy

The Examiner has rejected Claims 1, 2, 5-17, 24-37, 39-66, 72-87, 94-107, and 109-133 as allegedly obvious in view of Lacy. Lacy teaches a carrier system for a hydrophobic drug including a digestible oil and a surfactant for dispersing the oil. The surfactant includes a hydrophilic surfactant which inhibits in vivo lipolysis of the digestible oil, and a lipophilic surfactant capable of reducing the inhibitory effect of the hydrophilic oil. (col. 4, lines 1-14). Lacy further provides a method of improving the in vivo bioavailability of a hydrophobic drug from a composition comprising the drug dispersed or dissolved in a digestible oil. (col. 4, lines 21-26).

The Examiner has argued that Lacy teaches a carrier system for improving the bioavailability of a drug that is dispersed as well as dissolved in a digestible oil. The Applicants disagree with this assertion. It is clear from the language of Lacy at col. 4, lines 21-26 that a pharmaceutical composition including either a dispersed or a dissolved drug was contemplated, but not a single composition containing both. Furthermore, col. 15, lines 8-11 states that the hydrophobic drug is added to the liquids and mixed until either a homogeneous solution or suspension is prepared. Lacy clearly teaches only a single phase composition that is very different from a composition comprising two fractions, one that is dissolved and one that is dispersed as is required by the present claims. It is the Applicants' assertion that only impermissible hindsight in light of the present application would allow Lacy to be construed as teaching more than such a single phase composition.

It is the Examiner's opinion Lacy teaches the preparation of a composition in cols. 14 and 15 that involves the same steps as that described in Example 4 of the present application. The Applicants first assert that it is impermissible for the Examiner to base a rejection on a comparison between examples of the present application and examples of a cited reference. The rejection should properly compare the elements of the claims to the cited reference, and in the present case, the Lacy

reference does not teach or suggest a formulation as recited in Claim 1, namely a pharmaceutical composition having dispersed phase and a solubilized phase.

Furthermore, the Examiner has noted that Lacy does not teach the specific amounts of drug in each fraction according to Claim 1. The Examiner argues that it would have been obvious to one of ordinary skill in the art to optimize the various components of the formulation to achieve the desired release rate and bioavailability. The Applicants respectfully assert that it would not be obvious to one of ordinary skill in the art to adjust the ratios for the suspended and the solubilized fraction based on the teaching of Lacy because Lacy does not teach or suggest a composition with two fractions. How could one of ordinary skill in the art adjust ranges of two fractions of a drug in a composition based on a reference that teaches the inclusion of only a single portion of a drug in that composition?

Additionally, the Examiner has pointed out that Lacy teaches a solid, liquid, or semi-solid composition in col. 14. It is clear from the language of this section, however, that Lacy is referring to the form of the pharmaceutical composition as a whole, as the physical state of the composition is in relation to ambient temperature. (col. 14, lines 52-55). Such language also does not suggest a composition with two fractions.

Accordingly, Lacy does not teach or suggest each and every limitation of independent Claims 1 and 74. The Applicants respectfully request that these rejections be withdrawn.

Rejection in view of Lacy and Mezei

The Examiner further argues that Mezei provides the claim limitations of the independent claims of the present application that are missing from Lacy. Mezei teaches a pharmaceutical formulation comprising lipid vesicles including a biologically active compound therein, a saturated solution of the biologically active compound, and the biologically active compound in solid form. Though the reference does mention oral administration in a laundry list, it is primarily teaching topical formulations (col. 5; abstract). Mezei further states that the absorption of the active agent can be optimized by the formulation because of the active agent being present in solution and in association with the lipid vesicles (col. 5, lines 14-19).

The Mezei reference cannot be combined with the Lacy reference to arrive at the claims of the present invention. At best, such a combination would suggest

development of a solid form of the drug formulation encapsulated in liposomes. It would thus not be obvious to one of ordinary skill in the art to combine a reference requiring liposomal association with a solid drug with a reference teaching either a solubilized phase or a suspended phase to arrive at a pharmaceutical formulation having a solubilized fraction and a solid fraction in the formulation. Accordingly, the combination of Lacy and Mezei would not render obvious the limitations of independent Claims 1 and 74. The Applicants respectfully request that these rejections be withdrawn.

Accordingly, Applicants respectfully submit that Lacy, alone or in combination with Mezei, do not teach or suggest each and every element of the present invention. Moreover, the Applicants submit that the reference(s) does not contain sufficient teachings or suggestions to motivate one of ordinary skill in the art to modify and apply such teachings in arriving at the present invention. Therefore, Applicants submit that the rejection of the present claims in view of Lacy, alone or in combination with Mezei, is improper and respectfully request that it be withdrawn. Additionally, claims 2, 5-17, 24-37, 39-66, 72-73, 75-87, 94-107, and 109-133 are narrower in scope than the claims from which they depend, and are thus considered to be allowable along with claims 1 and 74.

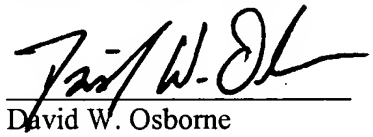
CONCLUSION

In view of the foregoing, Applicants believe that pending claims 1, 2, 5-17, 24-37, 39-66, 72-87, 94-107, and 109-133 present allowable subject matter and allowance thereof is respectfully requested. If any impediment to the allowance of these claims remains after consideration of the above remarks, and such impediment could be removed during a telephone interview, the Examiner is invited to telephone the undersigned attorney at (801) 566-6633 so that such issues may be resolved as expeditiously as possible.

Please charge any additional fees except for Issue Fee or credit any overpayment to Deposit Account No. 20-0100.

Dated this 1st day of June, 2006.

Respectfully submitted,



David W. Osborne
Attorney for Applicant
Registration No. 44,989

Of:

THORPE NORTH & WESTERN, LLP
8180 South 700 East, Suite 200
Sandy, Utah 84070
(801) 566-6633